K132209

510(K) SUMMARY (revised)

IPS e.max® CAD Abutment Solutions

Contact:	Donna Marie Hartnett, Director QA/Regulatory Affairs
Company:	Ivoclar Vivadent. 175 Pineview Drive, Amherst, NY 14228 (716) 691-0010
Date Prepared:	October 18, 2013
Proprietary Name:	IPS e.max® CAD Abutment Solutions
Classification Name:	Abutment, Implant, Dental Endosseous (872.3630)
Predicate Devices:	Sirona Dental CAD/CAM System (K111421) IPS e.max CAD (K051705) IPS e.max Press Abutment Solutions (K120053 and K124008)

OCT 3 1 2013

Device Description: IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. Titanium bases are a premanufactured prosthetic component directly connected to dedicated endosseous dental implants. The Titanium base is used for adhesion to mesostructures to restore function and esthetics in the oral cavity. IPS e.max CAD Abutment Solutions are lithium disilicate blocks in various sizes. One side of the block is mounted to a mandrel that will be inserted into the spindle's clamping chuck of the grinding machine. The connection geometry to titanium bases is prefabricated, i.e. already include in the shipped block. Connection geometries fit select Titanium Bases marketed by Straumann, Nobel Biocare and Biomet 3i as identified in the Intended Use section. The mesostructure is individually designed and milled using CAD/CAM Technology into the shape of a hybrid abutment or hybrid abutment crown as designed by the trained professional using the Sirona inLab and Cerec SW 4.2 (or higher) software.. The device serves as the esthetic mesostructure which is extraorally cemented onto a Titanium Base. The two piece abutment is mounted onto the implant and fixed with a screw.

Predicate Device: The predicate device to which IPS e.max® CAD Abutment Solutions has been compared is Sirona Dental CAD/CAM System(K111421). For this application, IPS e.max® CAD Abutment Solutions has been compared to its predicate with regard to chemical composition, performance data and indications for use. The comparison shows that IPS e.max® CAD Abutment Solutions is substantially equivalent to the predicate device.

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Intended Use:

IPS e.max CAD Abutment Solutions is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations. The system comprises three parts:

IPS e.max CAD ceramic structure,

Ti base and

CAD/CAM software

The IPS e.max CAD ceramic structure cemented to the Ti base is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants. The compatible Implant systems, Ti bases and CAD/CAM systems are shown below:

Implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Activem (K071370), Straumann Bone Level (K053088,), Biomet 3i Certain (K014235)

CAD/CAM Systems: Sirona inLab and Cerec SW 4.2 (or higher) software

Titanium bases:

Implant manufacturer	Implant System	Implant Diameter (mm)	TiBase	Sirona Ref.	Interface size
Nobel Biocare	Replace NP	3.5	NBRS 3.5	6282474	L
	Replace RP	4.3	NBRS 4.3	6282482	L
	Replace WP	5.0	NBRS 5.0	6282490	L
	Replace 6.0	6.0	NBRS 6.0	6282508	L
Nobel Biocare	Nobel Active NP	3.5	NB A 4.5	6208188	L
	Nobel Active RP	4.3 / 5.0	NB A 5.0	6208253	L
Straumann	Bone Level NC	3.3	S BL 3.3	6308154	L
	Bone Level RC	4.1 / 4.8	S BL 4.1	6308337	L
Biomet 3i	Certain	3.4	B C 3.4	6308048	S
	Certain	4.1	B C 4.1	6308097	L
	Certain	5.0	B C 5.0	6308121	L

For the titanium base Straumann Bone Level 3.3 L the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible.

Material Composition: The device is composed or proprietary lithium disilicate ($Li Si_{2}$) dental ceramic and is identical in composition to IPS e/max CAD (K051705).

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Technological Characteristics: The device design, i.e. delivery form, and intended use of IPS e.max CAD Abutment Solutions and the predicate device are the same. The materials comply with ISO 6872:2008 for Dental Ceramics. The composition of the subject device has been modified from the predicate, however, there are no ingredients in the subject device which pose any new issues of safety and effectiveness.

Scientific Concept: The underlying scientific concept is the use of an already introduced technology of a titanium base abutment combined with individually CAD/CAM fabricated ceramic prosthetics made from lithium disilicate, a material proven to be suitable for safe and effective dental restoratives.

Testing Summary: According to FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" may 12, 2004, fatigue testing has been performed for angled abutments.

Physical properties of IPS e.max CAD:

- CTE (100°C – 500°C) $10.5 \pm 0.5\ 10^{-6}/K$
- Flexural strength (Biaxial) $\geq$ 360 MPa (Test Method ISO 6872)
- Fracture toughness $\geq 2.0\ MPa\ m^{0.5}$ (Test Method ISO 6872)
- Chemical solubility ≤ 50 □g/cm^2 (Test Method ISO 6872)
- Crystallization temperature 840 – 850°C

Conclusion: IPS e.max CAD Abutment Solutions is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 31, 2013

Ivoclar Vivadent AG
C/O Donna Hartnett
Director of Quality Affairs/Regulatory Affairs
Ivoclar Vivadent, Incorporation
175 Pineview Dr.
AMHERST NY, 14228

Re: K132209
Trade/Device Name: IPS e.max® CAD Abutment Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: II
Product Code: NHA
Dated: August 6, 2013
Received: August 7, 2013

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, MS
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132209

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Ti base and
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Implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Activem (K071370), Straumann Bone Level (K053088, K062129, K060958), Biomet 3i Osseotite (K980549)

CAD/CAM Systems: Sirona inLab and Cerec SW 4.2 and above

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Andrew I. Steen -S
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Concurrence of CDRH, Office of Device Evaluation (ODE)